## REMARKS

Claim 1-17 are pending in the instant patent application. Claims 6, 9-14 and 16 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 1-5, 7, 8, 15 and 17 have been rejected. Claims 1 and 15 have been amended. Claim 17 has been canceled. New claims 18-27 have been added. Support for these amendments is provided in the specification at pages 15-17, 33-34 and Example 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

### I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement as set forth in the Communication mailed October 15, 2003. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 6, 9-14 and 16 without prejudice. Further, Applicants have amended the claims to be drawn to the elected sequences. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

**II. Rejection of Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph**

Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention lacks patentable utility. Further, these claims have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids for ovarian malignancy detection. Further, with respect to claim 17, the Examiner suggests that there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO:115 as a vaccine.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's suggestion that the specification is unclear with respect to the source of tissue of the nucleic acid sequence of SEQ ID NO:115 and the level of expression of SEQ ID NO:115 in cancer vs. normal tissue. The instant specification states at page 118, lines 22 through 26 that a CLASP5 marker such as SEQ ID NO:115 exhibits differential expression in cancer tissue thus making clear the levels of expression in cancer vs. normal tissue. Further, it is stated that the sequence must exhibit

specificity for the tumor tissue of interest, which in this case, as made clear throughout the rest of the specification is ovarian cancer tissue. Accordingly, the Examiner's basis for the rejection of claims 1-5, 7, 8, 15 is flawed.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:115 as being differentially expressed in ovary cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for ovarian cancer, thus satisfying the utility requirement.

Applicants have canceled claim 17 this mooting rejections relating to this claim.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is respectfully requested in light of the claim amendments and the above remarks.

**III. Rejection of Claim 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description**

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written

description requirement. In particular, the Examiner suggests that the specification fails to provide descriptive support for the generic claim to "a nucleic acid that selectively hybridizes to the nucleic acid comprising SEQ ID NO:115". The Examiner also suggests that the large genus of nucleic acids having at least 60% sequence identity to SEQ ID NO:115 is not supported by the written description of the instant application.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence hybridizes under stringent conditions and have defined these conditions in accordance with teachings at page 15-17. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 80% identity in accordance with teachings at page 33-34. Further, in accordance the teachings of Example 1, Applicants have amended claim 1 to state that the nucleic acid molecule is differentially expressed in ovarian cancer tissue.

Detailed methodologies for ascertaining sequences which meet the structural and functional limitations of the instant amended claims are set forth in the specification at page 14, line 3, through page 15, line 8, and page 15, line 17 through page 17, line 30 and Example 1. Further methods for assessing percent

sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequences of SEQ ID NO:112 through 115 and differential expression thereof in ovarian tumor tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

**IV. Rejection of Claim 14 under 35 U.S.C. § 112, second paragraph**

Claim 14 has been rejected under 35 U.S.C. § 112, second paragraph as the Examiner suggests that the claim does not recite a final process step which clearly relates back to the preamble. It is respectfully pointed out, however, that claim 14 was

withdrawn from consideration by the Examiner as being drawn to non-elected subject matter. Applicants have thus canceled claim 14, without prejudice, in the instant application, thereby mooting this rejection.

Withdrawal of this rejection of claim 14 under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

**V. Rejection of Claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. § 102(a)**

Claims 1, 2, 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 102(a) as being anticipated by a sequence with accession No. BF116062. The Examiner suggests that the sequence of accession no. BF116062 is 20.7% identical to SEQ ID NO:115, with base pairs 1 to 582 99.8% identical to base pairs 1139-1721 of SEQ ID NO:115. Thus, the Examiner suggests that the sequence with accession no. BF116062 will hybridize specifically to SEQ ID NO:115. Further, the Examiner suggests that this human cDNA was cloned into a vector and must have been used in host cells.

Claims 1, 2, 4, 5, 7 and 8 have also been rejected under 35 U.S.C. § 102(a) as being anticipated by a sequence with accession no. BE857462. The Examiner suggests that the sequence with accession no. BE857462 is 48.7% identical to SEQ ID NO:113 with base pairs 204 to 582 being 99.7% identical to base pairs 105 to

484 of SEQ ID NO:113. Further, the Examiner suggests that the sequence with accession no. BE857462 is 42.5% identical to SEQ ID NO:112 with base pairs 359 to 524 being 99.4% identical to base pairs 1 to 166 of SEQ ID NO:112.

Applicants respectfully traverse these rejections.

While the sequences of accession no. BF116062 and BE857462 may exhibit regions of similarity to SEQ ID NO:115 and 113 and 112, respectively, there are also large regions of disparity. Thus, these sequences are clearly different from the instant claimed invention. Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from these prior art sequences, Applicants have amended claim 1, part (c), to state that the nucleic acid molecule hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). Support for this amendment is provided in the specification at page 15, line 16, through page 17, line 30. The sequences of BF116062 and BE857462, with their regions of disparity would not hybridize under stringent conditions as now claimed.

Further, Applicants have amended part (d) of claim 1 to

state that the nucleic acid molecule has at least 80% sequence identity over the entire length of a nucleic acid molecule comprising SEQ ID NO:112, 113, 114 or 115 or a nucleic acid molecule encoding SEQ ID NO:221. Support for this amendment is provided at page 33, line 11, through page 34, line 15. Neither BF116062 nor BE857462 share this percentage of sequence identity with the claimed invention.

Thus, these references do not teach sequences with all the elements of the claimed invention and cannot anticipate the instant claimed invention.

Withdrawal of these rejections under 35 U.S.C. § 102(a) is therefore respectfully requested.

**VI. Rejection of Claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. § 102(b)**

Claims 1, 2, 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by accession No. AA156960. The Examiner suggests that accession No. AA156960 discloses a sequence which is 17.2% identical to SEQ ID NO:115 with base pairs 1 to 495 having 99.6% identity to base pairs 2240-2736 of SEQ ID NO:115. Thus, the Examiner suggests that the sequence with accession no. AA156960 will hybridize specifically to SEQ ID NO:115. In addition, the Examiner suggests that accession No.

AA156960 is 51.5% identical to SEQ ID NO:114 with base pairs 1 to 495 having 99.6% identity to base pairs 422-918 of SEQ ID NO:114. Thus, the Examiner suggests that the sequence with accession no. AA156960 will also hybridize specifically to SEQ ID NO:114. Further, the Examiner suggests that this human cDNA was cloned into a vector and that host cells were made.

Claims 1, 2, 4, 5, 7 and 8 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by accession No. AA088637. The Examiner suggests that accession No. AA088637 discloses a sequence which is 42.8% identical to SEQ ID NO:113 with base pairs 3 to 441 having 91.6% identity to base pairs 107-543 of SEQ ID NO:115. Thus, the Examiner suggests that the sequence with accession no. AA088637 will hybridize specifically to SEQ ID NO:113. In addition, the Examiner suggests that accession No. AA088637 (442 base pairs) is 31.3% identical to SEQ ID NO:112 with base pairs 255 to 441 having 87.8% identity to base pairs 1-185 of SEQ ID NO:112. Thus, the Examiner suggests that the sequence with accession no. AA088637 will also hybridize specifically to SEQ ID NO:113 and 112. Further, the Examiner suggests that this human cDNA was cloned into a vector and that host cells were made.

Applicants respectfully traverse these rejections.

While the sequences of accession no. AA156960 and AA088637 may exhibit regions of similarity to SEQ ID NO:112-115, there are also large regions of disparity.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from prior art teachings such as the sequences of accession no. AA156960 and AA088637, Applicants have amended the claim 1, part (c), to state that a nucleic acid molecule hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). Support for this amendment is provided in the specification at page 15, line 16, through page 17, line 30.

Further, Applicants have amended part (d) of claim 1 to state that the nucleic acid molecule has at least 80% sequence identity over the entire length of a nucleic acid molecule comprising SEQ ID NO:112, 113, 114 or 115 or a nucleic acid molecule encoding SEQ ID NO:221. Support for this amendment is provided at page 33, line 11, through page 34, line 15. Neither of the cited sequences share this percentage of sequence identity with the claimed invention.

Thus, these references do not teach sequences with all the

elements of the claimed invention and cannot anticipate the instant claimed invention.

Withdrawal of these rejections under 35 U.S.C. § 102(b) is therefore respectfully requested.

**VII. Rejection of Claims 1, 2, 4, 5, 7, 8, 15 and 17 under 35 U.S.C. § 102(e)**

Claims 1, 2, 4, 5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Rosen et al. (U.S. 2003/0108907). The Examiner suggests that Rosen et al. teach polynucleotides and polypeptides related to ovarian and breast cancers. Further the Examiner suggests that Rosen teach a polynucleotide with SEQ ID NO:947 (1593 base pairs) which is 77% identical to SEQ ID NO:112, 70.5% identical to SEQ ID NO:113, 94.4% identical to SEQ ID NO:114 and 55% identical to SEQ ID NO:115. Further, the Examiner suggests that Rosen et al. teaches human cDNAs and vectors and host cells comprising the polynucleotides, a kit for analyzing for the presence of the cancerous polynucleotide and administration of the polynucleotide as a vaccine.

Applicants respectfully traverse this rejection.

While the sequence of Rosen may exhibit regions of similarity to SEQ ID NO:112, 113, 114 and 115, there are also

regions of disparity. Thus, the sequence of Rosen is clearly different from the instant claimed invention.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention from the teachings of Rosen, Applicants have amended claim 1, part (c), to state that the nucleic acid molecule hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b). Support for this amendment is provided in the specification at page 15, line 16, through page 17, line 30. The sequence of Rosen, with regions of disparity would not hybridize under stringent conditions as now claimed.

Further, Applicants have amended part (d) of claim 1 to state that the nucleic acid molecule has at least 80% sequence identity over the entire length of a nucleic acid molecule comprising SEQ ID NO:112, 113, 114 or 115 or a nucleic acid molecule encoding SEQ ID NO:221. Support for this amendment is provided at page 33, line 11, through page 34, line 15. The sequence of Rosen does not share this percentage of sequence identity with the claimed invention.

Thus, Rosen does not teach a sequence with all the elements

of the claimed invention and cannot anticipate the instant claimed invention.

Withdrawal of these rejection under 35 U.S.C. § 102(e) is therefore respectfully requested.

**VIII. Rejection of Claim 15 under 35 U.S.C. § 102(b)**

Claim 15 has been rejected under 35 U.S.C. § 102(b) as being anticipated by GibcoBRL Catalog (p. 7-7, 1993-94). The Examiner suggests that this catalog teaches a kit with random primers which are suitable for DNA synthesis. Thus, the Examiner suggests that since any DNA can be amplified with such primers, they can be used to detect the nucleic acid comprising SEQ ID NO:115.

Applicants respectfully traverse this rejection.

MPEP §2131 is quite clear; to anticipate a claim the reference must teach all the elements of the claimed invention. Claim 15 is drawn to a kit for detecting a risk of cancer or presence of cancer in a patient. The kit comprises a means for determining the presence of a nucleic acid molecule comprising: (a) a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 221; (b) nucleic acid sequence of SEQ ID NO:112-115; (c) a nucleic acid sequence that hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at

least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b); or (d) a nucleic acid molecule having at least 80% sequence identity over the entire length of the nucleic acid molecule of (a) or (b). The vague teachings of the Gibco Catalog regarding a kit for random primer generation in no way teaches a means for detection of these specific nucleic acid molecules.

Thus, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

**IX. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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